

**Revised January 2008
Chesapeake Bay Program Quality Assurance
Guidelines and Requirements**

Quality assurance requirements for EPA grants and cooperative agreements are contained in 40 CFR Part 30.54 for universities and other non-profits, and 40 CFR Part 31.45 for States, tribal, and local governments, and Regional Order 5361.5 Location Identification Policy and Responsibilities. If an organization makes use of EPA financial assistance to operate environmental programs and projects that acquire, generate, compile, or use environmental data and technology, it must establish and implement a Quality System. A Quality System is a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The Quality System provides the framework for planning, implementing, and assessing the work performed by an organization and for carrying out required quality assurance (QA) and quality control (QC) activities. (ANSI, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*. American National Standard, ANSI/ASQC E4-1994.)

After receiving notification that a proposal has been accepted, the organization submits a description of their Quality System, typically in two formal documents: 1) Quality Management Plan, and 2) Quality Assurance Project Plan. EPA must review and approve all Quality Management and Quality Assurance Project Plans prior to the initiation of environmental data collection and/or compilation activities except under circumstances requiring immediate action to protect human health and the environment or operations conducted under police powers.

Quality Management Plan

The Quality Management Plan documents management practices used to ensure that the results of technical work are of the type and quality needed for their intended use. Elements to be addressed in a Quality Management Plan include: management and organizational structure; quality system description; personnel qualifications and training policies; procurement of items and services; documentation and records requirements; computer hardware and software standards; planning; implementation of work processes; evaluation of work performed; and quality improvement. The Quality Management Plan is sometimes viewed as the ‘umbrella’ document under which individual projects are conducted. The Quality Management Plan is then supported by project-specific QA Project Plans. **For long-term monitoring programs, the laboratory quality system should be documented in a Laboratory Quality Manual.**

Quality Management Plans must be prepared in accordance with *EPA QA/R-2: EPA Requirements for Quality Management Plans*, which is available on the worldwide web at www.epa.gov/quality1/qa_docs.html.

The Quality Management Plan must be approved internally by its Quality Assurance Manager (or equivalent) and the organization’s senior management, then submitted to the EPA Project Officer at least 60 days prior to the initiation of data collection or data compilation.

Prior to data collection or data compilation, the Quality Management Plan must be approved by the U.S. EPA Region 3 Quality Assurance Manager, U.S. EPA Science Center, Ft. Meade, MD 20755-5350.

An approved Quality Management Plan may be valid for up to five years unless there is a major program reorganization that affects quality assurance functions and structures in the organization. If an approved plan is expected to expire during the course of the grant, include a deliverable for the submission of a revised plan.

Organizations may be granted an exception or modification to the QMP requirement if they meet criteria which may include, but not be limited to, the following:

- **Small grants as defined by the *EPA Small Grants Policy*;**
- **One-time, short-term, and special projects or projects of limited scope; and**
- **Organizations generating, collecting, compiling and/or using environmental data for public education purposes.**

For certain grants and cooperative agreements, the Project Officer may allow the recipient to submit a combined Quality Management Plan/Quality Assurance Project Plan. The minimum EPA requirements for a Quality Management Plan and a Quality Assurance Project Plan must be included in the combined Plan.

Quality Assurance Project Plan

All work funded by EPA that involves the acquisition of environmental data generated from direct measurement activities, collected from other sources, or compiled from computerized data bases and information systems shall be implemented in accordance with an approved QA Project Plan. No work covered by this requirement shall be implemented without an approved Quality Assurance (QA) Project Plan available prior to the start of the work.

A QA Project Plan documents the technical and quality aspects of a project, including project planning, implementation, and assessment. It covers sampling design, sample collection, analytical methods, quality control, and data management activities. For small projects, the grant recipients may include the QA specifications in the scope of work or the work plan as long as all QA requirements are addressed. Specific requirements for quality assurance project plans are defined in *QA/R-5: EPA Requirements for Quality Assurance Project Plans* (EPA 1999), which is available on the worldwide web at http://www.epa.gov/quality1/qa_docs.html.

Specifications for water quality monitoring programs must adhere to the sampling and analytical procedures described in the most recent version of *Recommended Guidelines for Sampling and Analysis in the Chesapeake Bay Monitoring Program*.

http://www.chesapeakebay.net/pubs/quality_assurance/doc-EPA903-R-96-006.pdf

The plan shall be submitted to the EPA Project Officer along with the draft grant or assistance application, or listed as a deliverable to be received at least 30 days prior to the initiation of each data collection or data compilation activity. The QA Project Plan must be reviewed and approved by the Chesapeake Bay Program Office Quality Assurance Officer prior to the initiation of each data collection or data compilation activity.

All Quality Assurance Project Plans must be submitted in an electronic format, as these plans will be made directly accessible to the users of the generated data/information through the Chesapeake Information Management System (CIMS). For more information on CIMS, refer to http://www.chesapeakebay.net/cims/data_management_guidance_03.pdf.

For ongoing environmental data collection programs, the quality assurance project plans must be updated annually to ensure any changes to field, sampling handling and storage, laboratory analysis, quality control, and data management activities are accurately documented. The recipient should notify the Project Officer prior to changing the number of samples, the number of sites, or parameters measured. If no changes are needed to an existing quality assurance project plan, the grant recipient must provide written documentation (e.g., a letter) to the Project Officer that a review was conducted and no changes have occurred.

Should there be multiple programs involved in a grant or cooperative agreement, at the recipient's discretion, the recipient may either submit a single quality assurance project plan covering all of the programs or a separate quality assurance project plan for each program receiving grant or cooperative agreement funds.

All efforts must be made to produce data that is comparable to data collected previously and currently by other Chesapeake Bay Program grant recipients and partners. The recipient shall ensure the agencies, academic institutions, and/or consulting firms responsible for field sample collection and/or laboratory analysis of environmental samples collected using Chesapeake Bay Program funds or matching funds will participate in the Chesapeake Bay Program's Coordinated Split Sample Program and/or inter-laboratory sample comparison program. For more information on the Chesapeake Bay Program's **Quality Assurance** Program, refer to <http://www.chesapeakebay.net/qualityassurance.htm>.